

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jens PETERSEN

Title: **POLYACRYLAMIDE HYDROGEL FOR THE TREATMENT OF INCONTINENCE AND VESICOURETAL REFLUX**

Appl. No.: 09/938,667

Filing Date: 08/27/2001

Examiner: Blessing M. Fubara

Art Unit: 1618

Confirmation No. 2505

DECLARATION OF DAVID A. DIAMOND

UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, David A. Diamond, hereby declare as follows:

- (1) I am currently employed as an Associate Professor of Surgery (Urology) at Harvard Medical School and as an Associate in Urology at Children's Hospital Boston, in Boston, Massachusetts. I hold the degree of Doctor of Medicine and I am board-certified in the specialty of urology. My qualifications as an expert in urology are detailed in an appended curriculum vitae (APPENDIX 1).
- (2) I am not an inventor of the captioned application, and I have no personal interest in the disposition of the captioned application by the U.S. Patent and Trademark Office (PTO).
- (3) I have reviewed and believe that I understand the captioned application and its pending claims.

(4) I understand that a PTO action dated January 11, 2008 ("Office Action"), cites against the pending claims a Russian Patent No. 2,148,957 to Sknar. From my review of an English-language translation of the latter document (see APPENDIX 2), I understand the Sknar patent to disclose administration of polyacrylamide hydrogel into the ostium ureteris submucosa of the ureter for the treatment of vesicoureteral reflux ("VUR") in children.

(5) I understand that the PTO relies on the Sknar patent for the proposition that it was a known practice, when the captioned application was filed ("the critical date"), to inject a polyacrylamide hydrogel into the ostium of the ureter in order to impede the flow of urine. The PTO also has taken the position, I understand, that a person knowledgeable in urology (A) would have been motivated, at the critical date, to inject acrylamide hydrogel into the ostium of the ureter or into the urethra and (B) would have expected the hydrogel thus to act as a bulking material, increasing resistance to the flow of urine in the ureter or the urethra, thereby to treat urinary incontinence.

(6) Historically, some medical practitioners have applied injectable bulking substances, previously approved for the treatment of vesicoureteric reflux ("VUR") in children, to the treatment of very specific types of urinary incontinence in children, including total urinary incontinence due to neurogenic bladder (e.g., myelomeningocele) and congenital defects such as bladder exstrophy or epispadias. In these latter instances, however, the success in treating urinary incontinence with the injectable bulking agents has been poor (no greater than 50%) and apparently unrelated to the substance utilized (e.g., Teflon, silicone, collagen, dextranomer particles). By contrast, pediatric VUR is generally amenable to management with injectable agents (success rates of 80%).

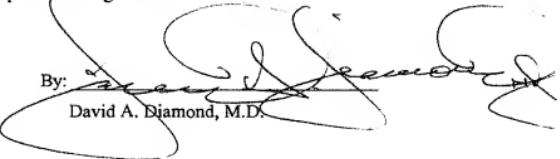
(7) This difference speaks to the very different pathology of total urinary incontinence versus VUR in children. Total urinary incontinence in children is typically due to the complete absence of a muscular sphincter mechanism at the bladder neck, either anatomically (as in bladder exstrophy or epispadias) or functionally (as in myelomeningocele or other neurological disorders). Vesicoureteral reflux, on the

other hand, is secondary to a weak flap-valve mechanism at the ureterovesical junction. This represents a simpler mechanism, that is more successfully corrected with the use of injectable bulking agents. Indeed, the most common types of urinary incontinence in children are not amenable to treatment with injectable bulking agents.

(8) Accordingly, I conclude that a person knowledgeable in urology, as of the critical date, would not have presumed or reasonably expected that a given demonstration of using a bulking agent to correct VUR, as the PTO finds in the Sknar patent, would be predictive of success in treating pediatric urinary incontinence with that bulking agent.

(9) I further declare that all the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements are so made punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 6/5/08

By: 
David A. Diamond, M.D.

Curriculum Vitae and Bibliography

PART I: General Information

Date Prepared: March 31, 2008

APPENDIX 1

Name: David Andrew Diamond, M.D.

Office Address: Department of Urology
Children's Hospital
300 Longwood Avenue
Boston, MA 02115

Home Address: 44 Columbine Road
Newton, MA 02459

Work E-Mail: david.diamond@childrens.harvard.edu **Work Fax:** 617-730-0474

Place of Birth: Cape May Court House, New Jersey, USA

Education

1970-1974 A.B. Princeton University, Princeton, NJ

1974-1978 M.D. The University of Rochester School of Medicine and Dentistry, Rochester, NY

Postdoctoral Training

1978-1980	Intern and Junior Resident	Surgery	The University of Vermont School of Medicine, Burlington, VT
1980-1981	Junior Assistant Resident	Urology	The Johns Hopkins University School of Medicine, Baltimore, MD
1981-1982	Clinical Research Fellow	Urology	The Johns Hopkins University School of Medicine, Baltimore, MD
1982-1983	Senior Assistant Resident	Urology	The Johns Hopkins University School of Medicine, Baltimore, MD
1983-1984	Chief Resident	Urology	The Johns Hopkins University School of Medicine, Baltimore, MD

7/84-12/84	Herbert Johnston Research Fellow	Pediatric Urology	The Alder Hey Children's Hospital, The University of Liverpool, Liverpool, England
12/84-6/85	Senior Registrar to Mr. Philip Ransley	Pediatric Urology	The Great Ormond Street Hospital for Sick Children and Institute of Urology, London, England
7/01-6/02	Fellow	Medical Ethics	Harvard Medical School

Licensure and Certification

1980	Maryland Medical License
1985	Massachusetts Medical License
1993	Rhode Island Medical License
1979	American Board of Medical Examiners
1986	American Board of Urology
1994	American Board of Urology
2004	American Board of Urology

Hospital or Affiliated Institution Appointments

1996-	Associate in Urology	Children's Hospital, Boston, MA
1996-	Consultant	Brigham & Women's Hospital, Boston, MA
1996-	Consultant	Metrowest Medical Center, Framingham, MA
2005-	Associate Clinical Ethicist	Children's Hospital, Boston, MA

Academic Appointments

1985-1988	Assistant Professor	Urology & Pediatrics	University of Massachusetts Medical Center, Worcester, MA
1988-1994	Associate Professor	Urology & Pediatrics	University of Massachusetts Medical Center, Worcester, MA
1994-1996	Professor	Urology & Pediatrics	University of Massachusetts Medical Center, Worcester, MA
1996-	Associate Professor of Surgery	Urology	Harvard Medical School

Major Visiting Appointments

1989	Visiting Professor	Brown University, Providence, RI
1991	Visiting Professor	University of Florida, Gainesville, FL
1994	Visiting Professor	University of Minnesota, Minneapolis, MN
1995	Visiting Professor	University of Varese, Varese, Italy
1996	Visiting Professor	Medical College of Wisconsin, Milwaukee, WI
1996	Visiting Professor	Long Island Jewish Hospital, New Hyde Park, Long Island, NY
1996	Visiting Professor	Hospital of Melegnano, Milan, Italy
1999	Visiting Professor	International Meeting on Pediatric Urology, Varese, Italy
1999	Visiting Professor	Hospital of Melegnano, Milan, Italy
2004	Visiting Professor	Henry Ford Hospital, Detroit, MI

Major Administrative Responsibilities

1987-1995	Co-Director Residency Program in Urology	University of Massachusetts Medical Center
1987-1995	Clerkship Director in Urology	University of Massachusetts Medical Center
1989-1995	Senior Scholars Committee, Chairman	University of Massachusetts Medical Center
2006-	Physician's Leadership Council	Children's Hospital, Boston
2006-	Joint Oversight Committee	Children's Hospital, Boston
2006-	Medical Peer Review Committee	Children's Hospital, Boston

Major Committee Assignments

University of Massachusetts Medical Center

1987-1989 Infection Control Committee
1989-1995 Senior Scholars Committee, Chairman
1989-1995 Clinical Years Committee
1989-1995 Surgical Education Committee
1990-1992 Hospital Executive Committee
1993-1995 Search Committee- Chairman of Plastic Surgery
1993-1995 Treatment Issues Committee
1993-1995 Steering Committee- Children's Medical Center

Children's Hospital, Boston

1996-2003 Library Committee
1997-2000 Ethics Committee
2005- Ethics Committee
2005- Ethics Advisory Committee
2005- Clinical Research Executive Committee (CREC) NIH Roadmap Subcommittee
2006 Physician's Leadership Council
2007 Physician's Leadership Council – Nominating Committee

National

2005 NIH/NIDDK Pediatric Urology Research Strategy Planning Committee

Professional Societies

1984 Johns Hopkins Medical and Surgical Association, Member

1985 Massachusetts Medical Society, Member

1987 Society for Pediatric Urology, Fellow
 2003-present Research Prize Committee
 2005-2008 Alternate Representative to American College of Surgeons

1987 American Urological Association, Member
 2002 Program Committee, New England Section, Chairman
 2004-2006 By Laws Committee, New England Section
 2005 Program Committee, New England Section
 2006 Program Committee, New England Section
 2007 Program Committee, New England Section
 2008 Program Committee, New England Section

1987 Society of University Urologists, Member

1988 American Academy of Pediatrics, Fellow
 1991 Scientific Research Prize Committee, Urology Section
 1994 Program Committee, Urology Section
 1995 Program Committee, Urology Section
 1996 Program Committee, Urology Section, Chairman
 1996 Annual Meeting Program Committee, Chairman, Urology Section
 1997 Program Committee, Urology Section
 1997-1999 Publications Committee, Urology Section, Chairman
 1997-2000 Executive Committee, Urology Section
 1999-2002 Membership Committee, Urology Section, Chairman
 1999-2008 Registry Review Committee, Urology Section
 2002-2008 Registry Review Committee, Urology Section, Chairman

1989 American Association of Pediatric Urology, Member

1992 Massachusetts Association of Practicing Urologists, Member

1993 Société Internationale D'Urologie, Member
 2006 Consensus Committee on Adolescent Genital Problems

1993 European Society for Pediatric Urology, Member

1994 Society of Genitourinary Reconstructive Surgeons, Member

1995 Boston Surgical Society, Member

1996 Norfolk District Medical Society, Member

1996 American College of Surgeons, Fellow
2005-2008 Society for Pediatric Urology Representative (Alternate)

Community Service Related to Professional Work

1987-present	Interviewer	Alumni Schools Committee, Princeton University
1991-1996	Board Member	Worcester Jewish Community Center
1999-present	Volunteer Member	Physicians for Peace
2006	Board of Directors Member	Temple Emeth, Chestnut Hill, MA

Editorial Boards

1994-1998	Editorial Board	Journal of Urology, Pediatrics Section
2003	Guest Editor	British Journal of Urology International, vol. 92, supplement 1

Ad Hoc Reviewer

1990-	Journal of Urology
1993-	Urology
1997-	British Journal of Plastic Surgery
1999-	Digital Journal of Urology
2000-	Journal of the American Academy of Dermatology
2001-	Journal of Pediatrics
2003-	African Journal of Urology
2004-	Asian Journal of Andrology
2004-	Pediatrics
2004-	Urologic Oncology: Seminars and Original Investigations
2005-	Journal of Pediatric Urology
2005-	Journal of Endourology
2006-	Pediatric Nephrology
2007-	Journal of Experimental Pathology
2007-	The Lancet
2007-	Medical Journal of Australia
2007-	BJU International
2007-	Nature Clinical Practice Nephrology
2008-	Nephrology
2008-	International Brazilian Journal of Urology

Awards and Honors

1965	Eagle Scout, Silver Palm
1967	First Prize Pennsylvania Newspaper Publishers Newsboy of the Year Award
1974	The Princeton Fencing Award, Princeton University
1982	First Prize Mid-Atlantic Section, American Urological Association Essay Contest – Laboratory Research
1984	Second Prize, American Urological Association Essay Contest – Laboratory Research
1987	First Prize, Biennial Alumni Presentations, Brady Urological Institute, Johns Hopkins Hospital
2006	First Prize, Clinical Research, American Academy of Pediatrics Section on Urology, Annual Meeting

PART II: Research, Teaching, and Clinical Contributions

Narrative report of research, teaching, and clinical contributions.

I am a pediatric urologist doing clinical care and research. I have had a particular interest in disorders of sexual differentiation which has developed further as an aspect of my interest in medical ethics. In addition, I have been involved in clinical research on the adolescent varicocele and have done translational research on endoscopic correction of vesicoureteric reflux using autologous chondrocytes. I also have a major teaching commitment within the Medical School, regionally and nationally, and have been heavily involved in the American Academy of Pediatrics at a national level.

I have written extensively about disorders of sexual differentiation, including the definitive chapter in the last two editions of Campbell's Textbook of Urology. During my fellowship in medical ethics at Harvard Medical School, I selected as my research project study of the ethical dilemmas related to gender assignment in newborns with ambiguous genitalia and developed a survey instrument to study the knowledge, attitudes and behavior of pediatric urological colleagues nationally about this issue. These results were presented at the 2004 AAP national meeting and published in the Journal of Pediatrics (reference 95). As a result of our work and that of others, colleagues nationally have adopted a particularly careful approach to assignment of gender and urological management of children with disorders of sexual differentiation.

Since 2005 I have served as Associate Clinical Ethicist at Children's Hospital. I have continued to write about ethical aspects of intersex disorders (Clinical Communications 1 & 2) and have been selected as Director of a Children's Hospital consultation service that provides a coordinated subspecialty approach to patients with disorders of sexual differentiation.

My appointment at Children's Hospital Boston has afforded me a robust clinical practice, such that I perform over 400 surgical procedures and see over 3,600 outpatients per year. While this has included referrals for intersex disorders, among the more common referrals has been adolescent varicocele and vesicoureteric reflux.

In 2001 I began as principal investigator of the Adolescent Varicocele study at Children's Hospital, with the goal of improving our understanding of this widespread lesion. We embarked upon a long-term study to determine whether or not early surgery improved outcomes in terms of semen analysis and ultrasound calculated testicular growth. This represents the first national prospective, randomized study of adolescent varicocele. We have enlisted partner institutions, including Children's Hospital of Philadelphia, Vanderbilt Children's Hospital, Children's Hospital of Wisconsin, and Rainbow Babies Hospital. To date, our research has focused on the indications for surgical correction of varicocele, including the accuracy of our clinical tools for determining impaired growth of the involved testis and more recently its correlation with semen analysis results (references 65, 73, 80, 84, 92, Review 8). Our work on this subject received first prize in clinical research at the 2006 Annual Meeting of the American Academy of Pediatrics Section on Urology. While it is difficult to quantitate changes in clinical practice nationally, I believe that our studies have encouraged colleagues to be more selective in recommending surgery.

I was principal investigator in the clinical trial at Children's Hospital of the use of autologous chondrocytes to correct vesicoureteric reflux endoscopically (references 57, 68, 79, 82). This study

represented the first clinical application of tissue engineering in Urology. The results of our study demonstrated this technique to be effective. However, funding for the project was discontinued when an alternative substance became the first to receive FDA approval.

I have enjoyed teaching at all levels – of medical students, residents, fellows and colleagues – and the teaching leadership roles that I have held. While at the University of Massachusetts I was co-Director of the Urology Residency for eight years and responsible for training and evaluation of residents and all pediatric urology training. I directed the Urology Clerkship for 4th year medical students and chaired the Senior Scholars Committee for the Medical School. At Children's Hospital, in my teaching of urology residents from the four Boston urology residency programs and pediatric urology fellows, I have emphasized safety, conservatism and surgical humility.

I have also enjoyed educational writing – both formally in peer reviewed journals and texts and also more informally in AUA Update Series, Dialogues in Pediatric Urology and Society of Pediatric Urology newsletters. Over the years I have been surprised by the impact that my informal writings have had on urology residents nationally.

At a national level I have been most heavily involved in leadership of the American Academy of Pediatrics Section of Urology. I have particularly enjoyed serving as annual program Chair (1996) as well as Chairman of three committees. I have also served on committees for the NIH/NIDDK and the Society for Pediatric Urology. In the course of my career I have seen pediatric urology develop from a small, somewhat informal subspecialty to the only subspecialty recognized by the American Board of Urology, in 2005, with a certificate of added qualification. This has formally established pediatric urology as a subspecialty clinically, academically and politically. It is my hope that in some way my own professional activities have contributed to our subspecialty's recognition.

Funding Information.

1986	Biomedical Research Support Grant, University of Massachusetts Medical Center. The Effects of Cyclosporin A on Male Fertility, Principal Investigator.
1997-2002	Reprogenesis Inc., Endoscopic Correction of Vesicoureteric Reflux Using Autologous Chondrocytes, Principal Investigator and Director of Clinical Trial.
1999-2001	Urosurge Inc., Use of a Transurethral, Self-Detachable Balloon System for Urinary Incontinence in Pediatric Patients, Principal Investigator and Director of Clinical Trial.
2001	American Association of Pediatric Urologists Research Grant, Varicocele in Adolescents.

Report of Current Research Activities.

Principal Investigator, Adolescent Varicocele Study, Children's Hospital, Boston, MA.

Director, Children's Hospital, Disorders of Sexual Differentiation Consultation Service.

Report of Teaching.

1. Local contributions

Local invited teaching presentations

Medical students

1985-1995 University of Massachusetts Medical Center.

Pediatrics Grand Rounds – UTI in Children, Intersex Disorders, Prenatal Hydronephrosis, Undescended Testis

Surgery Grand Rounds – Male Epispadias, Undescended Testis, Bladder Exstrophy, Laparoscopy in Pediatric Urology

I was an invited lecturer for Grand Rounds in each of these departments annually. The attendees of the Grand Rounds included medical students, residents and faculty. The preparation time for each of these lectures was approximately 10 hours.

Graduates

1985-1995 University of Massachusetts Medical Center
Urology Grand Rounds

I was an invited lecturer for these Grand Rounds monthly. My topics included all aspects of pediatric urology such as urinary tract infection in children, vesicoureteric reflux, prenatal hydronephrosis, the undescended testis, hypospadias and bladder exstrophy. The preparation time for these lectures was approximately 10 hours.

1985-2006 Harvard Medical School
Countway Urology Rounds

During the 21 years that I have been in the Boston area I have presented regularly at Countway Urology Rounds, the major teaching conference for urology residency, urology residents, urology faculty in the Greater Boston area. Lectures varied from topics including "paratesticular parodies" to varicocele and intersex disorders. These lectures would require between 10 and 20 hours to prepare.

1996-2006 Children's Hospital, Boston.
Uroradiology Lectures

Congenital Abnormalities – Duplication Anomalies, Undescended Testis, Prenatal Hydronephrosis

Neonatal Urological Emergencies

Adolescent Varicocele

Endoscopic Correction of Reflux

ALARA Concept in Diagnosis of Vesicoureteric Reflux

I have been invited to present uroradiology lectures bi-annually. The audience includes Radiology and Urology faculty, residents, and medical students. The preparation time for each of these lectures has been approximately 10 hours.

2002 Children's Hospital Nephrology Fellows Conference
Endoscopic Correction of Reflux

The audience included Nephrology fellows and Urology residents. The preparation time was approximately 10 hours.

Faculty

2002 Children's Hospital Boston, Surgical Grand Rounds
Adolescent Varicocele.

The audience included Surgical faculty, residents and medical students. The preparation time was approximately 12 hours.

2000, 2003 Pediatrics Grand Rounds, Metrowest Medical Center

Roughly every three years I am invited to present Pediatrics Grand Rounds to pediatric faculty at Metrowest Medical Center. These topics have included voiding dysfunction in children, urinary tract infection and vesicoureteric reflux and its treatment. The preparation time has been approximately 10 hours.

1996-2005 Boston University Urology Grand Rounds

Once a year I have presented at Boston University's Urology Grand Rounds to medical students and graduate students and faculty on topics such as urethral reconstruction, endoscopic correction of reflux, duplication anomalies of the urinary tract. These presentations have required approximately 8 hours to prepare.

Continuing medical education courses

Faculty

2003 Advances in Pediatric Health Care Post Graduate Course, Beverly Hospital
Neonatal Urological Emergencies

The audience included Pediatric faculty and residents. The preparation time has been approximately 10 hours.

2005 Advances in Pediatric Health Care Post Graduate Course, Metrowest Medical Center
Urinary Tract Infections in Children

The audience included Pediatric faculty and residents. The preparation time has been approximately 10 hours.

2006, 2007 Harvard Medical School course on pediatric and adolescent gynecology.

In this review course for gynecology faculty regionally and nationally, my topic is urological problems in girls. Preparation time for this lecture is approximately 10 hours.

2006, 2007 Harvard Bioethics Course.

Invited Discussion Group Leader.

Advisory and supervisory responsibilities

Graduates

1996-2001 Clinical Supervisor Urology Clinic, Children's Hospital, 150 hours per year.

Teaching leadership

Medical students

1987-1995 Clerkship Director in Urology, University of Massachusetts Medical Center

Urology was one of a group of required surgical sub-specialties at University of Massachusetts Medical Center. We had one or two students rotating on the service at any given time. Urology became a popular specialty and a number of medical students from University of Massachusetts have entered the field.

1989-1995 Chairman, Senior Scholars Committee, University of Massachusetts Medical Center

In 1989 a new program was developed at University of Massachusetts Medical Center which enabled seniors to concentrate in their area of intended residency training which included two clinical rotations and one month of research. I was chairman of this committee and responsible for enabling students to identify an advisor in their field of interest. I was also responsible for coordinating the research activities for the Senior Scholars in the Surgery Department. At the end of the year, I organized a program whereby the Senior Scholars presented their research to the Medical School faculty. On graduation, those seniors who had completed a Senior Scholars project were recognized accordingly by the Dean of the Medical School.

Graduates

1987-1995 Director of Residency Program in Urology, University of Massachusetts Medical Center

The University of Massachusetts Medical Center Residency Program in Urology was approved in 1985 and at that time it was the first new Urology program in the United States in 10 years. I assumed the co-directorship of the Residency in 1987. It rapidly developed into a highly respected and competitive program, attracting excellent candidates nationally.

Names of advisees or traineesPediatric Urology Fellows

1994-1996	Dix Poppas, MD	Richard Rogers Family Associate Professor of Pediatric Urology, Weill Cornell Medical Center, New York, NY
1995-1998	Martin Kaefer, MD	Assistant Professor of Urology, Riley Hospital for Children, Indianapolis, IN
1996-1998	Joseph Borer, MD	Assistant in Urology, Children's Hospital, Boston, MA
1997-1999	John Park, MD	Associate Professor & Chief of Pediatric Urology, University of Michigan, Ann Arbor, MI
1998-2000	Hiep T. Nguyen, MD	Assistant Professor Surgery (Urology), Children's Hospital, Boston, MA
1999-2001	Jonathan Roth, MD	Assistant Professor of Urology, Temple University School of Medicine, Philadelphia, PA
2000-2002	Hans G. Pohl, MD	Staff Urologist, National Children's Hospital, George Washington University, Washington, DC
2001-2003	Roger De Filippo, MD	Assistant Professor of Urology, University of Southern California & Los Angeles Children's Hospital, Los Angeles, CA
2001-2004	Dawn L. McLellan, MD	Assistant Professor of Urology, Dalhousie University Medical Center, Halifax, Nova Scotia
2002-2005	Chester Koh, MD	Assistant Professor of Urology, University of Southern California & Los Angeles Children's Hospital, Los Angeles, CA
2002-2006	Carlos Estrada, MD	Instructor in Surgery (Urology), Children's Hospital, Boston, MA
2002-2007	Richard Lee, MD	Instructor in Surgery (Urology), Children's Hospital, Boston, MA

2. Regional, national or international contributions

Invited presentations

Regional

1994 Invited lecturer. Brown University Update in Urology, Colby College. Neonatal Urological Emergencies.

 Faculty/invited lecturer. New England Section, American Urological Association. Management of the Impalpable Testis.

1995 Invited lecturer. Brown University Update in Urology, Newport, RI. Laparoscopy in Pediatric Urology.

1997 Faculty/invited lecturer. New England Section, American Urological Association. Laparoscopy in Pediatric Urology.

2005 Faculty/invited lecturer. New England Section, American Urological Association. Endoscopic Treatment of Vesicoureteric Reflux.

National

1988 Invited lecturer. Ferris Memorial Lecture in Pediatric Urology. Wilmington Medical Center, Wilmington, DE. The Undescended Testis.

1989 Invited lecturer. Post Graduate Course in Pediatric Urology. University of Michigan, Ann Arbor, MI. Prenatal Hydronephrosis.

1991 Faculty/lecturer. Society for Pediatric Urology, American Urological Association. The Undescended Testis.

1993 Faculty/lecturer. Post Graduate Course in Pediatric Urology. American Urological Association. Prenatal Hydronephrosis and Urinary Tract Infection and Vesicoureteric Reflux in Children.

1994 Faculty/invited lecturer. Society of Genitourinary Reconstructive Surgeons. Male Epispadias Repair.

1995 Faculty/invited lecturer. Urodynamics Society. American Urological Association. Bladder Neck Reconstruction.

1997 Faculty/invited lecturer. Society for Pediatric Urology, American Urological Association.
Male Epispadias Repair.

1998 Faculty/invited lecturer. American Urological Association.
Optimal Management of the Impalpable Testis.

2000 Faculty/invited lecturer. American Urological Association.
Adolescent Patient-Varicocele.

Faculty/invited lecturer. American Society of Pediatric Nephrology.
Prenatal Hydronephrosis.

Faculty/invited lecturer. Southern California, Permanente Urology Symposium.
Laparoscopy in Pediatric Urology and Neonatal Urological Emergencies.

2002 Faculty/invited lecturer. Section of Urology, American Academy of Pediatrics.
Academic Authorship – The Harvard Guidelines.

2004 Faculty/invited lecturer. American Urological Association.
Adolescent Varicocele.

Faculty/invited lecturer. Post graduate course, Pediatric Urology, American Urological Association.
Adolescent Varicocele and Prenatal Hydronephrosis.

2005 Faculty/invited lecturer. Post graduate course, Pediatric Urology, American Urological Association.
Prenatal Hydronephrosis and Adolescent Varicocele.

Faculty/invited lecturer. Section of Urology, American Academy of Pediatrics.
Microsurgical Spermatic Vein Ligation for Varicocele.

2006 Faculty/invited lecturer. The ALARA Concept in Pediatric International and
Fluoroscopic Imaging.
Society for Pediatric Radiology.

Faculty/invited lecturer. Post graduate course, Pediatric Urology, American Urological Association.
Prenatal Hydronephrosis and Adolescent Varicocele.

2007 Faculty/invited lecturer. Post graduate course, Pediatric Urology, American Urological Association.
Prenatal Hydronephrosis and Adolescent Varicocele.

2008 Faculty/invited lecturer. Society for Pediatric Urology.
Adolescent Varicocele.

2008 Faculty/invited lecturer. Society for Fetal Urology.
Ethical Issues in Fetal Urology.

2008 Faculty/invited lecturer. American Urological Association Basic Science Review Course.
Disorders of Sexual Differentiation.

International

1999 International Meeting on Pediatric Urology, Varese, Italy.
Endoscopic Treatment of Vesicoureteric Reflux with Autologous Chondrocytes.

Faculty/invited lecturer. Egyptian Urological Association.
Neonatal Urological Emergencies.

2000 Faculty/invited lecturer. Egyptian Urological Association.
Adolescent Varicocele.

2002 Faculty/invited lecturer. Egyptian Urological Association.
Endoscopic Treatment of Vesicoureteric Reflux with Autologous Chondrocytes.

2003 Faculty/invited lecturer. Brazilian Congress of Pediatric Surgery and Pediatric Urology.
Adolescent Varicocele, Endoscopic Treatment for Vesicoureteric Reflux with Autologous Chondrocytes, and Ethical Dilemmas in Gender Assignment in Newborns with Intersex.

2004 Faculty/invited lecturer. Simpson-Smith Symposium, Great Ormond Street, Hospital for Sick Children, Institute of Child Health, London, UK.
Adolescent Varicocele.

Faculty/invited lecturer. SIU Oncology Meeting/Egypt.
Transitional Cell Carcinoma of the Bladder in Children.

2005 Faculty/invited lecturer. Bolivian Congress of Pediatric Urology.
Adolescent Varicocele, The Undescended Testis, Prenatal Hydronephrosis, and Robotic Surgery in Pediatric Urology.

2007 Faculty/invited lecturer. II World Congress of the Federation of Associations of Pediatric Surgeons, Buenos Aires, Argentina.
Hypospadias and Disorders of Sexual Differentiation.

2007 Faculty/invited lecturer. Bolivian Congress of Pediatric Urology.
An Argument Against Endoscopic Treatment of VUR.
Transitional Cell Carcinoma in Children.
Disorders of Sexual Differentiation.

Professional and educational leadership role

Regional

2002 Chairman, New England Section, Annual Meeting Program Committee

One of the major responsibilities of Program Chairman was to select speakers for this meeting and I chose the first guest lecturer in medical ethics to speak at a urology meeting regionally or nationally as well as the first lecturer in robotic surgery to speak at the regional meeting.

National

1996 Chairman, American Academy of Pediatric Urology Section, Annual Meeting Program Committee.

In designing this meeting a number of important changes were introduced, most notably the first video forum for description of innovative surgical techniques in pediatric urology.

1997-1999 Chairman, American Academy of Pediatrics Urology Section, Publications Committee.

My appointment as Chairman of the Publications Committee dovetailed with my participation on the inaugural editorial board of the pediatric section of the Journal of Urology. Establishment of a dedicated pediatrics section to our major urological journal was considered pivotal in establishing pediatric urology as a formal subspecialty. As Chairman of the Publications Committee, I was responsible for insuring that those papers selected for presentation at the national meeting at the American Academy of Pediatrics would be subsequently submitted for publication to the Journal of Urology or another peer reviewed journal. As a result of the committee's work, the pool of submitted manuscripts available to promote education and clinical expertise in our subspecialty was considerably strengthened.

1997-2000 Executive Committee, American Academy of Pediatrics Urology Section.

During my tenure on the Executive Committee tremendous accomplishments were made by the Urology Section of the AAP. A coordinating council was developed which oversaw all of the major political societies within the specialty in order to promote subspecialty status for pediatric urology. This proved, in time, to be extremely effective. The annual meetings during this period of time grew in size and stature. The national meeting of the AAP became recognized as the finest international pediatric

urology meeting of the year. The number of fellowship programs increased from thirteen to approximately twenty. And, pediatric urology was awarded a designated section within the Journal of Urology.

2002-2008 Chairman, American Academy of Pediatrics Urology Section, Registry Review Committee.

The objective of this committee is to promote and review pediatric urological patient registries. A significant aspect of our committee's work recently has been to coordinate the governance of registries across our specialty amongst all major societies such that no two registries are in competition and to engender the broadest clinical, academic and financial support for pediatric urology registries nationally.

Report of Clinical Activities.

Description of clinical practice.

My practice at Children's Hospital is an active one, such that I perform over 400 surgical procedures and see 3,600 outpatients per year. My major interests have been in pediatric andrology, the adolescent varicocele in particular, and disorders of sexual differentiation. I have started the first prospective study of adolescents with varicocele nationally at Children's Hospital. I also have maintained an active interest in medical ethics, in general, and as it relates to pediatric urology in my service as Associate Clinical Ethicist at Children's Hospital.

Clinical contributions.

Program development: Adolescent Varicocele Study

Clinical Supervisor, Urology Clinic, Children's Hospital,
1996-2001

Director, Disorders of Sexual Differentiation Consultation
Service, 2006

Part III: Bibliography

Original Articles

1. Diamond DA, Jeffs RD, Marshall FF. Control of Prolonged Benign Renal Hematuria by Silver Nitrate Instillation. *J Urol* 1981;18(4):337-41.
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